May 2004

VA IRB Bulletin Board

Deadlines for Submission to IRB

The IRB staff has been evaluating the deadlines for IRB materials, and would like to make all of you aware of the **new deadlines**, which we hope will make your lives a little easier. A calendar with all specific dates for submitting materials will shortly be posted at www.visn20.med.va.gov/portlandrd, but here is a general overview of the deadline structure. Please check the website to confirm deadlines.

- All new studies and investigator-initiated changes are still required by the **20th of the Month (or following business day if on a weekend)**
- For items reviewed by **IRB #1** which were tabled and required changes, the requested changes should be turned in by the **last Monday of the Month*** in order for the revised documents to be reviewed at the next meeting. (*however, in May, August and November, 2004, items are due by the **fourth Monday of the Month** due to the short turn around for IRB agenda materials.)
- For items reviewed by **IRB #2** which were tabled and required changes, the requested changes should be turned in by the **first Monday of the next Month*** in order for the revised documents to reviewed at the next meeting. (*however, in May, August & November, 2004, items are due the **last Monday of that Month** due to the short turn around for IRB agenda materials.)

**Please note that the required education components must be completed by all applicable parties before the IRB will review any studies, investigator-initiated changes, etc.

The IRB staff is working hard to get correspondence back to investigators and study coordinators after the meeting in order to allow enough time for a thoughtful revision to be submitted. The IRB staff aim to have the correspondence sent to investigators in 7-10 calendar days. Questions regarding these deadlines should be referred to Sola at x52885.

Submission of Revised Consent Forms/Documents

When submitting revised consent forms to address changes requested by the IRB, please send an electronic version of the revised consent (using the "track changes" function in Word) to **PVAMC-IRB@med.va.gov**. This will allow the IRB staff to send the changes to the IRB reviewers more quickly and ensure the information highlighted is still visible for the reviewers after photocopying.

HIPAA Authorization Language

The PVAMC HRPP HIPAA policy has been updated to reflect that it is optional to include the HIPAA Authorization language in the informed consent form. If the HIPAA Authorization language is not included in the VA Informed Consent form, the research participant must sign the Authorization for the Release of Protected Health Information for Research Purposes, if protected health information is being created, accessed, used or disclosed in the research study.

Pharmacy Issues

The **Investigational Drug Information Record** (VA Form 10-9012) should be completed whenever a protocol involves the use of an **investigational new drug** (a drug with an approved NDA (new drug application) from the FDA), a FDA **approved drug** that is being used for an unapproved therapeutic indication or **a comparator drug** with an approved indication.

The Investigational Drug Information Record is a document that will be entered into a study participant's chart at the time of the initial dispensing of the study drug. The form is an information tool that is designed to profile the study drug and provide pertinent information about the drug to practitioner's outside of the study group that are responsible for the patient's care.

Filling out the 10-9012 can be a challenging task because the intention behind the information requested is not always clear.

The PVAMC Research Pharmacy Staff is here to help you. If you need assistance in filling out your VA Form 10-9012 please contact the Research Pharmacy at x55543

Updating of Study Personnel

When new staff join a research team, or other staff leave, make sure that the following are promptly submitted to the IRB so that the staff can be updated and new staff can begin working on the study:

- Project Revision/Amendment Form
- Certificates showing completion of the education requirements.
- Completion of credentialing requirements.
- A copy of the answers to appropriate sections of the IRQ.